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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,903	12/08/2004	Catharina Svanborg	bjs-4984-4	7669
23117	7590	05/28/2008	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			ROOKE, AGNES BEATA	
			ART UNIT	PAPER NUMBER
			1656	
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			05/28/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

<b>Application No.</b> 10/506,903	<b>Applicant(s)</b> SVANBORG ET AL.	
<b>Examiner</b> AGNES B. ROOKE	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 25 April 2008.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-8, 11-14, 19-21, 23, 24, 27-34 and 36 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 29-34 and 36 is/are allowed.
- 6)  Claim(s) 1-8, 11-14, 19-21, 23, 24, 27 and 28 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/25/2008 has been entered.

The amendments to the claims filed on 04/25/2008 have been acknowledged.

### ***Status of Claims***

Claims 1-8, 11-14, 19-21, 23, 24, 27-34, and 36 are pending and under consideration. Claims 9, 10, 15-18, 22, 25, 26, and 35 are cancelled. Claim 36 is new.

### ***Objections and Rejections withdrawn***

All objections and rejections not presented in this office action were withdrawn in view of the amendments to the claims or cancellation of the rejected claims.

The rejection of claims 1-3, 5, 13, 14, 18, 19, 20, 23, and 26-30 under 35 U.S.C. 102(b) as being anticipated by Swensson et al., Conversion of  $\alpha$ -lactalbumin to  $\alpha$ -lactalbumin a protein inducing apoptosis, PNAS (April 11, 2000), vol.97, no.8, p. 4221-4226 is withdrawn because Swensson et al. teach that the specific fatty acid C18:1 (oleic acid) was a necessary cofactor to convert native lactalbumin to its active

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form, where the converted form of lactalbumin is named HAMLET, and the oleic acid is excluded from the invention as currently claimed.

The rejection of claims 1-5, 13, 14, 18, 19, and 26-30 under 35 U.S.C. 102(b) as being anticipated by Hakansson et al., A folding variant of  $\alpha$ -lactalbumin with bactericidal activity against *Streptococcus pneumoniae*, *Molecular Biology*, 2000, 35(3), pages 589-600 is withdrawn because Hakansson et al. teach that native lactalbumin could be converted to the active form only in the presence of fatty acid C18:1 (oleic acid), see page 593, right column, 3<sup>rd</sup> paragraph, and the instant invention excludes oleic acid as a cofactor.

The rejection of claims 1, 6-8, 29, 31, and 32 under 35 U.S.C. 103(a) as being unpatentable over Swensson et al., Conversion of  $\alpha$ -lactalbumin to  $\alpha$ -lactalbumin a protein inducing apoptosis, *PNAS* (April 11, 2000), vol.97, no.8, p. 4221-4226 in view of Permyakov et al., Mutating aspartate in the calcium-binding site of  $\alpha$ -lactalbumin: effects on the protein stability and cation binding, *Protein Engineering*, vol.14, No.10, pp. 785-789, 2001 is withdrawn because Swensson et al. teach that the specific fatty acid C18:1 (oleic acid) was a necessary cofactor to convert native lactalbumin to its active form, where the converted form of lactalbumin is named HAMLET, and the oleic acid is excluded from the invention as currently claimed.

**New Rejections necessitated by Amendments to the claims**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11-14, 19-21, 23, 24, and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 is indefinite because it states: "wherein the cofactor is an unsaturated C16-C18 fatty acid." This claim is indefinite, because it is not clear whether the C16 to C18 fatty acids are bonded together in a structure or whether they represent the range of fatty acids ranging from 16 to 18 carbons, for example. Further, it is not clear whether the "at least one double bond in the cis configuration" is only present in the C16 or only in C18 fatty acid if the C16-C18 are bound together.

Dependent claims 2-8, 11-14, 19-21, 23, 24, 27, and 28 are included in this rejection because they depend from claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 11-14, 19-21, 23-24, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants amended claims 1 and 5 to refer to a cofactor “with at least one double bond in the cis configuration.” That phrase constitutes a new matter because “at least one double bond in the cis configuration” represents unlimited number of double bonds in such a cis configuration, and no support of such invention was taught in the original disclosure. Further, the specification on pages 3, 18, and 24, Applicants discuss structures with a double bond in cis configuration, but no additional information is provided regarding structures with at least one double bond in cis configuration.

Further, the cofactor represented in claim 1 as C16-C18 constitutes a new matter because such structure representing fatty acids were not presented in the original disclosure.

Dependent claims 2-4, 6-8, 11-14, 19-21, 23, 24, 27, and 28 are included in this rejection because they depend from rejected base claim 1.

If to the contrary, Applicants are required to specifically point out where such teachings supporting “at least one double bond in the cis configuration” and C16-C18 fatty acids are present in the disclosure.

Claims 1-8, 11-14, 19-21, 23, 24, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, Applicants claim cofactor that is an unsaturated C16-C18 fatty acid with at least one double bond in the cis configuration.

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MPEP § 2163 states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

In the instant invention, Applicants refer to a broad genus of C16-C18 fatty acids with at least one double bound in the cis configuration where the structure excludes oleic acid C18:1:9.

When analyze the claims under the written description requirement, one skilled in the art must evaluate what structures are disclosed to support the instant claims and whether the structures correspond with their function.

The instant specification discloses different examples where the only effective fatty acid that activates native lactalbumin to its active HAMLET form is oleic acid, for example. The disclosure does not pint out specifically which other fatty acids in the range of structure containing 16 or 17 or 18 carbons would be as effective.

Therefore, upon reviewing the disclosure, Applicants did not effectively describe the multiplicity of species that would represent such a broad genus of fatty acids having 16 and 17 and 18 carbons that can be effective as a cofactor converting native lactalbumin to active HAMLET form. Therefore, there is no structure to function relationship and thus nexus of such requirement for the written description purposes.

### ***Conclusion***

Claims 29-34 and 36 are allowable. No other claims are allowed.  
**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded

of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone

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number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Karen Cochrane Carlson, Ph.D./

Primary Examiner, Art Unit 1656